REMARKS AND RESPONSES TO DETAILED ACTION

1. *Examiner's point #1, Acknowledgement of cancellation of applicants claim 11:* No action needed

2. *Examiner's point #2, incorrect filing date listed by applicant:* Appropriate correction completed by Applicant.

3. *Examiner's point #3, Claims 2 and 9 are rejected, 35 USC §112:* the Applicant cancels claims 2 and 9.

4. *Examiner's point #4. Claims 6-10 are rejected as being indefinite, 35 USC §112:* Applicant cancels claims 9 and 10. Applicant thanks the Examiner for showing the Applicant how to be more definitive with claim 6. Claim 6 is modified to be narrowed ("a frequency" is replaced by "a specific frequency selected to"), to be dependent on claim 1 and to be more definitive (the "such as" followed by narrowing language was removed) on order to meet the requirements defined by the examiner. Based on these changes, the Applicant appeals the rejection of claims 6, 7 and 8.

1. *Examiner's point #5, Claims 1, 2, 4 and 5 are anticipated by Wolfinbarger 35 USC §102:* Claims 2, 4 and 5 are cancelled by Applicant. Applicant narrows claim 1 to reduce the maximum frequency to 9,000 Hz so as to avoid any possibility of a

perception of overlapping Wolfinbarger's 20,000 Hz minimum, the lowest accepted value for Wolfinbarger's ultrasonic sound. Applicant also adds clarifying language on the nature of the chamber and the process. Based on these changes, the rejection of claim 1 under 35 USC §102 is then appealed by the Applicant based on the following **ONE POINT OF LACK OF ANTICIPATION AND THREE (3) POINTS OF NOVELTY:**

5. **Wolfinbarger does not sufficiently anticipate Bogert.** In order to sufficiently anticipate an invention a "single reference must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention". Crown Operations International, Ltd. v. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed. Cir. 2002); In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). The anticipating reference "must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Wolfinbarger does not provide the teaching necessary for a person of ordinary skill in the field to anticipate Bogert, further supported by the fact that no one is using Bogert, despite its superior results.

5.1. **This language for Bogert's claim 1 distinguishes Bogert over Wolfinbarger under section 102 because Wolfinbarger does not teach to using "acoustic sound**

energy in the range of 20 cycles per second to 9,000 cycles per second". Wolfinbarger only teaches and discusses ultrasonic sound in the frequencies of 20,000 to 50,000 Hz. The frequencies claimed by Bogert in claim 1 are in the range of 20 Hz to 9,000 Hz and these frequencies are never mentioned by Wolfinbarger. Bogert's claim 1 is thus novel and the Applicant appeals the rejection of claim 1 under 35 USC §102 (for the reasoning as to why it is nonobvious to extend Wolfinbarger's frequency range see §103 discussion in section 6 below).

5.2. **This language for Bogert's claim 1 distinguishes Bogert over Wolfinbarger under section 102 because Wolfinbarger does not teach to using a "treatment chamber".** The first claim of Bogert refers specifically to a "treatment chamber". A "chamber" is defined as "a natural or artificial enclosed space" by the dictionary. All the ultrasonic cleaners referred to by Wolfinbarger throughout his patent are Branson models which have rectangular cleaning "beakers" or "basins" which have their tops open to the atmosphere. Wolfinbarger specifically defines his term "cleaning container" as the "beaker" of a Branson ultrasonic cleaner. Wolfinbarger never uses the terms "chamber" or "enclosed container". These open topped "beakers" are not enclosed and are not "chambers". Wolfinbarger does not anticipate the "chambers" of claim 1 of Bogert and Bogert's claim 1 is thus novel.

5.3. **This language for Bogert's claim 1 distinguishes Bogert over Wolfinbarger under section 102 because Wolfinbarger does not teach to using a container "filled with fluid".** All of the prior art illustrated in Wolfinbarger shows a container only partially filled with fluid. Wolfinbarger does not teach the container must be filled with fluid as a container doesn't have to be filled with fluid to work with ultrasonic sound, ultrasonic sound will clean the exterior of grafts in a partially filled container. Wolfinbarger does not anticipate the "filled with fluid" of claim 1 of Bogert and Bogert's claim 1 is thus novel.

6. *Examiner's point #6, Claims 6, 9 and 10 are unpatentable over Wolfinbarger as being obvious 35 USC §103:* Claims 9 and 10 are cancelled by applicant; claim 6 is narrowed and modified as above (paragraph 4 above) to be more definitive and to be dependent of claim 1 of Bogert. Claim 1 has also been changed (paragraph 5 above). Because claim 6 is now a dependent claim on claim 1, both claims need to be considered when discussing the nonobvious nature of Bogert's claim 6. Based on these changes, the rejection of claim 6 (and by extension claim 1) is appealed by the Applicant for the following **TWELVE (12) REASONS**:

6.1. **Not a Result Oriented Variable in Wolfinbarger for claim 6:** With reference to Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1080), Wolfinbarger does not recognize or teach that graft treatment optimization is a function of harmonics (or even sound intensity), and therefore the parameter optimized in claim 6 of Bogert was not recognized in the prior art to be a result- effective variable (re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)).

6.2. **Lack of Overlapping Range for Wolfinbarger for claims 1 and 6:** Because claim 6 of Bogert has been made dependent on claim 1 of Bogert, Bogert does not "overlap or lie inside ranges disclosed by the prior art" of Wolfinbarger, Wolfinbarger teaching 20,000 Hz to 50,000 Hz, Bogert claiming 20 Hz to 9,000 Hz; re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). If Wolfinbarger's use of ultrasonic cavitation cleaning (20,000 Hz to 50,000 Hz) cannot be extended to Bogert's use of oscillatory acoustic sound energy cleaning at a frequency of 20 Hz to 9,000 Hz, based on the "Graham Factors" listed below, then Wolfinbarger cannot be extended to Bogert's claim of the use of harmonics (claim 6) or acoustic sound energy (claim 1) in the range of 20 Hz to 9,000 Hz.

6.3. **"Graham Factors"** The Applicant then further appeals the rejection of claim 6 (and, by inference, claim 1) due to the following analysis of the "Graham Factors" (Graham v. John Deere Co., 383 U.S. 1 (1966)) for nonobviousness for Wolfinbarger vis-à-vis Bogert :

6.4. The Differences between the Claimed Invention and the Prior Art;

6.4.1. **Wolfinbarger's Ultrasonic Sound (20,000 Hz to 50,000 Hz) cleans by Cavitation; Bogert's Acoustic Sound Energy of 20 Hz to 9,000 Hz (claims 1 and 6) cleans by a different nonobvious unexpected mechanism, namely fluid oscillation:** There is a significant difference in the art described by Wolfinbarger and the claims of Bogert. Wolfinbarger describes in detail how the ultrasonic sound produces cavitation and how this cavitation cleans the grafts on their exterior. The fact that ultrasonic sound cleans by cavitation is well known to those skilled in the field. The fact that audible sound (20 Hz to 20,000 Hz) does not typically produce cavitation is well known and makes it nonobvious to those skilled in the art that audible sound would be an effective cleaning method. The Applicant unexpectedly found that audible acoustic energy cleans by creating an oscillating, back and forth; relatively large scale fluid movement in the tiny channels inside the solid matrix of the graft, thus cleaning the graft better and faster than ultrasonic sound can clean a graft. The use of audible sound as claimed in claim 1 of Bogert is thus nonobvious.

6.4.2. **Wolfinbarger doesn't use a "treatment chamber" as stated in Bogert's Claim 1 (and thus dependent claim 6) and as such, wouldn't work with lower frequencies:** This distinction is extremely important; a "chamber" works well in conjunction with audible sound to clean the internal surface of grafts while a non-enclosed "beaker" would prevent audible sound from cleaning the internal matrix of the grafts (the oscillation would dissipate at the surface of the beaker). Since ultrasonic sound cleans the external surface of grafts in both enclosed "chambers" and open "beakers" equally well (ultrasonic cavitation does not require an enclosed chamber), the distinction between "chambers" and "beakers" with reference to audible sound is nonobvious (see 5.2 above).

6.4.3. **Wolfinbarger does not use a container which is "filled with fluid", as stated in Bogert's claim 1 (and thus dependent claim 6) and as such, wouldn't work with lower frequencies.** All of the prior art illustrated in Wolfinbarger shows a container only partially filled with fluid. The ultrasonic sound of Wolfinbarger will clean the exterior of grafts in a partially filled container. Audible sound requires a filled chamber, something which is nonobvious (see 5.3 above).

6.4.4. **Wolfinbarger teaches away from the Bogert:** Wolfinbarger teaches 40,000 to 47,000 Hz as being the optimum frequency in his 20,000 to 50,000 Hz range, thus indicating a higher frequency is better. Bogert claims the much lower frequencies of 20 Hz to 9,000 Hz. A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference... would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

6.5. Scope and Content of Prior Art:

6.5.1. **Lack of Prior Literature on Cleaning using Audible Sound:** Ultrasonic sound is used in hundreds of thousands of cleaning applications throughout all industries but the Applicant could find no reference to the use of audible sound to clean or permeate any small device or item (claim 1 of Bogert). While there are thousands of articles written over the past 50 years on the effectiveness of ultrasound (above 20,000 Hz) to clean objects, there appears to be no literature on cleaning the interior of small articles with audible sound (20 Hz to 20,000 Hz), even though audible sound works quite well. The use of audible sound for cleaning is thus nonobvious.

6.5.2. **Unexpected Prototyping Results:** When this audible sound process (claim 1 of Bogert) was prototyped it was expected that thick cow bone would take many hours to obtain some limited permeation. Unexpectedly and surprisingly the cow bone was cleaned very thoroughly in only thirty two minutes under less than ideal conditions (no harmonic resonance was present). This reduction to practice occurred on September

18th 2002, at Virginia Commonwealth University Sound Labs with three graduate students under the direction of Tim Cameron PhD, under a non-disclosure agreement.

6.5.3. **Wolfinbarger Process doesn't clean the Solid Interior Matrix of the Graft, the Process of Bogert does clean the Interior and is Superior:** The oscillating movement of acoustic sound energy (Bogert) in the range of 20 Hz to 9,000 Hz penetrates and thoroughly cleans the tiny channels in the solid interior matrix of grafts very rapidly and thoroughly, while the cavitation of ultrasonic acoustic energy (Wolfinbarger) above 20,000 Hz does not clean the solid interior matrix of grafts either rapidly or thoroughly; ultrasonic cavitation only cleans the exposed exterior surfaces of the graft (cavitation cannot occur inside a solid graft matrix). Ultrasonic sound in the frequency range above 20,000 Hz cannot alone produce a sterile tissue; audible sound alone in the range of 20 Hz to 9,000 Hz can produce a sterile tissue. This superiority of audible sound is nonobvious to anyone who has ordinary skill in the field.

6.6. The Level of Ordinary Skill in the Prior Art;

6.6.1. **No Tissue Processor has Recognized the Superiority of Audible Sound:** Many graft processors have applied ultrasonic energy to clean grafts for many years (Tutogen, Regeneration Technologies, Lifenet, Musculoskeletal Transplant Foundation, to name just a few). Not one processor that the Applicant is aware of uses audible sound. Despite being experts in the field, not one graft processor has recognized the clear superiority of audible sound over ultrasonic sound for cleaning bacteria and other material from the tiny channels in the solid interior matrix of the grafts. Ultrasonic sound (above 20,000 Hz) alone cannot produce a sterile tissue; acoustic sound energy at a frequency of 20 Hz to 9,000 Hz can produce a sterile tissue with no augmentation and this is nonobvious to those skilled in the art.

6.7. Objective Evidence of Nonobviousness:

6.7.1. **Long-felt but unsolved needs: Patients continue to get infections from grafts:** Quote: "The FDA has been working to make human tissues safer since it first started regulating the tissue industry in 1993." "In 2001, for example, a 23-year-old Minnesota man died four days after receiving a transplant of bone and cartilage to reconstruct his knee. He had acquired a deadly infection from toxic bacteria in the tissue..... In 2002, five tissue recipients in the United States were believed to be infected by hepatitis C from a single donor's tissues. And in 2003, contaminated corneas resulted in infections and vision loss in two people." (FDA Consumer Magazine, May-June 2005 Issue)

6.7.2. **Failure of others: No one using only ultrasonic acoustic energy has met the FDA requirements for Sterility:** As of this date, despite many years of trying, no graft process which uses only ultrasonic energy has been able to claim sterility to the satisfaction of the FDA. The reason for this is that all these ultrasonic processes leave bacterial contamination inside the graft, where the ultrasonic cavitation cannot reach. Acoustic sound energy, as defined in claim 1 of Bogert, can remove this contamination and can create a sterile graft and this fact is nonobvious to those skilled in the art.

7. *Examiner's point #7, Claims 3 and 8 are unpatentable over Wolfinbarger combined with Rowe et al as being obvious 35 USC §103:* Claims 3 and 8 are

dependent on claim 1 and claim 6, both of which have been narrowed and clarified. So by extension claims 3 and 8 have been narrowed and clarified. Claims 3 and 8 have also been rewritten for clarity: Based on the rewrites of claims 1, 3, 6 and 8 by the applicant, the rejection of claims 3 and 8 is appealed by the Applicant for the following **EIGHT (8) REASONS**:

7.1. **Lack of a Logical Reason to Combine References and Each Reference is Individually Complete:** When an obviousness determination is based on a combination of prior art references, there must be a showing of a "teaching, suggestion, or reason" to do so. See Carella v. Starlight Archery, 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986). ("Obviousness cannot be established by combining the teachings of the prior art, absent some teaching, suggestion or incentive supporting the combination."); Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1012, 217 USPQ 193, 199 (Fed. Cir. 1983) ("It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve [a desired result]."), In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000) ("Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."); In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.").

There is no suggestion, teaching or reason to combine these technologies in these two patents or in other literature. Rowe et al does not suggest, teach or reason to the "grafts" of Wolfinbarger, Wolfinbarger does not suggest, teach or reason to the "skin" of Rowe et al. Rowe et al does not suggest, teach or reason to the "cleaning" or "removal" of materials of Wolfinbarger and Wolfinbarger does not suggest, teach or reason to the "transdermal assay of analyte and transdermal transport" of Rowe et al. The record must provide a teaching, suggestion, or reason to combine Rowe et al's "transdermal assay and transport on the skin" with Wolfinbarger's "cleaning of bone grafts" in the prior art. The absence of such a suggestion to combine is dispositive in an obviousness determination. See SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 886-87, 8 USPQ2d 1468, 1475 (Fed. Cir. 1988). The showing of combinability, in whatever form, must be "clear and particular." Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617.

There is no recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by this combination. In re Semaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). "That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of the ordinary skill in the art to combine the teachings of the references to make the claimed invention" Ex Parte Levengood, 28 USPQ 2d 1300 (PTOBA&I 1993).

7.2. Graham Factors for the Combined Rowe et al and Wolfinbarger Patents The Applicant then further appeals the rejection of claims 3 and 8 due to the following analysis of the Graham Factors for Wolfinbarger combined with Rowe et al vis-à-vis Bogert:

7.2.1. The Differences between the Claimed Invention and the Prior Art of Wolfinbarger and Rowe et al;

7.2.1.1. **Use of Audible sound and Tartini tones in dependent claims 3 and 8 (and independent claim 1) of Bogert is nonobvious over Rowe et al and Wolfinbarger**: Rowe et al teaches that sound created by Tartini tones can augment transdermal transport. Rowe et al does not teach that any sound, including that created by Tartini tones, can kill or remove (i.e. "clean") viruses, bacteria or any material from anything. The Wolfinbarger patent teaches that only ultrasonic sound cleans and kills viruses and bacteria by cavitation. The basis of the Bogert patent is a new teaching that the relatively large scale oscillatory movement of audible sound (and only audible sound) cleans viruses, bacteria and other material completely from a graft. The acoustic sound energy frequency of the first claim of Bogert is thus nonobvious. If this is nonobvious, then using acoustic sound energy which is created as Tartini tones to kill, remove or clean, claims 3 and 8, is also nonobvious.

7.2.2. Scope and Content of Prior Art:

7.2.2.1. Lack of Prior Literature on Cleaning via Audible Sound: see 6.5.1 above.

7.2.2.2. Unexpected Prototyping results: see 6.5.2 above

7.2.2.3. **Wolfinbarger Process combined with Rowe et al would not clean the Solid Interior Matrix of the Graft. The Process of Bogert does and is thus Superior:** See 6.5.3 above

7.2.2.4. **The single small paragraph in Rowe et al on Tartini Tones is vague, ambiguous, and incorrect.** A Tartini Tone is either the difference between or the sum of two frequencies; it is not "intermediate between the two", as Rowe et al teaches. Rowe et al also fails to teach to how to utilize the Tartini Tones.

7.2.3. The Level of Ordinary Skill in the Prior Art;

7.2.3.1. **No tissue processor has recognized the superiority of Audible Sound and has combined Rowe et al with Wolfinbarger and utilized Tartini tones to clean grafts**: see 6.6.1 above.

7.2.4. Objective Evidence of Nonobviousness;

7.2.4.1. Long-felt but unsolved needs: Patients continue to get infections from grafts: see 6.7.1 above.

7.2.4.2. Failure of others: **No one using ultrasonic acoustic energy and/or audible Tartini tones has met the FDA requirements for Sterility**: see 6.7.2 above.

8. *Examiner's point #8, Claim 7 is unpatentable over Wolfinbarger combined with Bishop as being obvious 35 USC §103:* Claim 7 is dependent on claim 1 and claim 6, both of which have been narrowed and clarified (see above). So by extension claim 7 has been narrowed and clarified. Based on the rewrites of claims 1 and 6, the rejection

of subordinate claim 7 is appealed by the Applicant for the following **TEN (10) REASONS**:

8.1. Lack of a Logical Reason to Combine References and Each Reference is Individually Complete: (See 7.1. for case law). When an obviousness determination is based on a combination of prior art references, there must be a showing of a "teaching, suggestion, or reason" to do so. There is no such suggestion, teaching or reason in these two patents or the literature. Bishop does not suggest, teach or reason to the "grafts" of Wolfinbarger, Wolfinbarger does not suggest, teach or reason to the "tissue inside of a human (or other animal) body" of Bishop. Bishop does not suggest, teach or reason to the "cleaning" or "removal" of materials of Wolfinbarger and Wolfinbarger does not suggest teach or reason to the "damaging", "disrupting" or "breaking up" of Bishop. The record must provide a teaching, suggestion, or reason to combine Bishop's "disrupting, damaging and breaking up of tissue inside of a human (or other animal) body" with Wolfinbarger's "cleaning of bone grafts" in the prior art. The absence of such a suggestion to combine is dispositive in an obviousness determination.

There is no recognition, expressly or impliedly in either reference, the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). "That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of the ordinary skill in the art to combine the teachings of the references to make the claimed invention" Ex Parte Levengood, 28 USPQ 2d 1300 (PTOBA&I 1993). (see 7.1. above).

8.2. Graham Factors for the Combined Bishop and Wolfinbarger Patents The Applicant then further appeals the rejection of claim 7 due to the following analysis of the "Graham Factors" for Wolfinbarger combined with Bishop vis-à-vis Bogert:

8.2.1. The Differences between the Claimed Invention and the Prior Art:

8.2.1.1. **Use of sound between 600 and 6000 Hz of dependent claim 7 (and the use of 20 Hz to 9,000 Hz of independent claim #1) of Bogert is nonobvious over Bishop and Wolfinbarger**: Bishop teaches that specifically ultrasonic sound kills viruses by very small scale and rapid oscillatory movement, heating and cavitation. Bishop does not teach that audible sound (600 Hz to 6,000 Hz of claim 7 and the 20 Hz to 9,000 Hz of claim 1 of Bogert) can kill or remove (i.e. "clean") viruses or bacteria. The Wolfinbarger patent only teaches that ultrasonic sound cleans and kills viruses and bacteria by cavitation. Neither Bishop nor Wolfinbarger teaches that audible sound (the 600 Hz to 6,000 Hz of claim 7 and the 20 Hz to 9,000 Hz of claim 1 of Bogert) kills or cleans viruses or bacteria from anything by any mechanism. The basis of the Bogert patent is a new teaching that the relatively large scale oscillatory movement of audible sound cleans viruses and bacteria (and other materials) completely from a graft. The claim for 600 Hz to 6,000 Hz of dependent claim 7 (and the use of 20 Hz to 9,000 Hz of independent claim #1) of Bogert is thus nonobvious.

8.2.1.2. **Neither the Bishop nor Wolfinbarger teach the "treatment chamber" of Bogert's claim 1 and thus the combination of the two wouldn't work.** Since claim 7 is ultimately dependent on claim 1, this distinction is important and nonobvious. See 6.4.2 above.

8.2.1.3. **Neither Bishop nor Wolfinbarger teach a container which is "filled with fluid" as does the claim 1 of Bogert and thus the combination of the two wouldn't work.** Since claim 7 is ultimately dependent on claim 1, this distinction is important and nonobvious. See 6.4.3. above.

8.2.2. Scope and Content of Prior Art:

8.2.2.1. Lack of Prior Literature on Cleaning via Audible Sound: see 6.5.1 above.

8.2.2.2. Unexpected Prototyping results: see 6.5.2 above

8.2.2.3. **Wolfinbarger Process combined with Bishop wouldn't clean the Solid Interior Matrix of the Graft. The Process of Bogert does clean the interior and is thus Superior:** See 6.5.3 above

8.2.3. The Level of Ordinary Skill in the Prior Art;

8.2.3.1. **No tissue processor has recognized the superiority of Audible Sound and combined Wolfinbarger with Bishop**: see 6.6.1 above.

8.2.4. Objective Evidence of Nonobviousness:

8.2.4.1. Long-felt but unsolved needs: Patients continue to get infections from grafts: see 6.7.1 above.

8.2.4.2. Failure of others: No one using the acoustic energy of Wolfinbarger and Bishop combined has met the FDA requirements for Sterility: see 6.7.2 above.

Examiner's list of prior art: All three pieces of prior art listed by the examiner: Patent 2,970,073 to Prange, Patent 3,401,690 to Martin and Application 2004/0037735 to DePaula et al, all have the same differences and Graham factors as Wolfinbarger, Bishop and Rowe et al (see above).

The applicant respectfully requests that, if the claims are again rejected upon any combination of references, that the examiner include an explanation, in accordance with M.P.E.P. § 706.02 Ex Parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1988) and Ex Parte Levengood, supra, "a factual basis to support his conclusion that would have been obvious" to make the combination.

Conditional Request for Constructive Assistance

Applicant has amended the claims of this application so that they are proper. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. 2173.02 and 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very respectfully:

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Certificate of Facsimile Transmission. I certify that on the date below I will fax this paper to GAU 1744 of the US Patent and Trademark Office at 571-273-8300.

May 2, 2006 David L. Bogert